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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,344	10/15/2001	Chad A. Mirkin	00-713-i22	6529

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EXAMINER	
RILEY, JEZIA	

ART UNIT.	PAPER NUMBER
1637	

DATE MAILED: 04/10/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/981,344	MIRKIN ET AL.	
	Examiner	Art Unit	
	Jezia Riley	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22 and 433-444* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-8,11-21 and 442-444* is/are rejected.

7)☒ Claim(s) *3,9,10,22 and 433-441* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *12* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

2. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Giles et al. (WO 92/04469).

Giles a method to detect the presence of nucleic acid sequences by agglutination of a generic particle reagent. The method utilizes specific binding partner coated particles (pages 3-6, for example). The particles can be any particulate insoluble material capable of being coated with a member of a specific binding pair. Examples of particles include gold. The sample is generally of biological origin and the target nucleic acid can be from PCR. Assay kits are provided which comprise specific binding partner coated particles, means for sample preparation, means for generation of species according to the invention (see claims).

3. Claims 1, 2, 4, 6, 11-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Olson (WO 90/02205).

Olson discloses a method for determining the presence or absence of nucleic acid sequences (DNA or RNA) in a sample. A sample to be assayed for nucleic acid sequences of interest is combined with two mutually non complementary probes. Kits are also described (page 7-9 and claims). The hybridization and agglutination steps can occur sequentially or simultaneously (page 12). Detection can be carried out visually using the unaided eye (page 31). At least two types of particles can be used (page 33). The nucleic acid sequence is any type of biological sample, which is viewed to be inclusive of instant claims 12-18 (page 12-13).

4. Claims 1, 2, 4-8, 11-17, 19-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Yguerabide et al. (6,214,560).

Yguerabide et al. discloses a method that includes specifically associating any one or more analytes in the sample with a scattered-light detectable particle, illuminating any particle associated with the analytes with light under conditions which produce scattered light from the particle and in which light scattered from one or more particles can be detected by a human eye with less than 500 times magnification and without electronic amplification. The method also includes detecting the light scattered by any such particles under those conditions as a measure of the presence of the analytes (abstract).

Yguerabide et al. discloses a method of light illumination and detection named "DLASLPD" (direct light angled for scattered light only from particle detected) disclose an analyte assay using gold particulate label for specific detection of one or more

analytes in a sample. One or more analytes in a sample can be detected and measured by detection and/or measurement of one or more of the specific light scattering properties of metal-like particles. (Summary of the Invention). For example, a certain nucleic acid analyte is composed of about 100 nucleic acid bases and is present in a sample. The sample is prepared so that this nucleic acid is in a single stranded form. Then two or more unique single-stranded "probe" nucleic acid sequences are added to the sample where these different probes bind to different regions of the target strand. Each of these probes has attached to one or more particles (col. 74). Further, the particles can form different types of aggregates that can be detected visually or instrumentally in a microscope or through macroscopic observation or measurements without having to separate free from analyte bound particles. The type of aggregates formed depends on the size of the cross-linking agent or agents and their valency and on the type of binding agent attached to the particle. Aggregates can range from two particles to many. The method can be used in a multi-analyte detection in the microarray format. For many years, metal particles including gold and silver have been used as both contrast enhancement agents or light absorption labels in many different types of analytic and/or diagnostic applications. Yguerabide et al. has also determined the following: (1) one or more analytes in a sample can be detected and measured by detection and/or measurement of one or more of the specific light scattering properties of metal-like particles. These light scattering properties include the intensity, wavelength, color, polarization, angular dependence, and the RIFSLIW (rotational individual fluctuations in the scattered light intensity and/or wavelengths) of the

scattered light. One or more of these properties of particle scattered light can be used to provide information regarding the analytes in the sample; (2) by varying the size, and/or shape and/or composition of a metal-like particle in various combinations, one or more of the light scattering properties can be adjusted to generate more easily detectable and measurable light scattering signals; (3) illumination and detection of the metal-like particles of certain size, shape, and composition with DLASLPD provides a highly sensitive and easy to use method to detect and measure metal-like particles by their light scattering properties. The method provides for single particle detection with easy to use and inexpensive apparatus means; (4) the DLASLPD methods can be used with particle counting and/or integrated light intensity measurements to provide for detection and measurement of the particles across wide concentration ranges; (5) the use of refractive index enhancement methods provides for enhancement of a particle's light scattering properties, and/or decreases in non-specific light background; (6) the use of DLASLPD video contrast enhancement methods can provide for more sensitive detection in many different types of samples and diagnostic assay formats. Low particle surface density (less than 0.1 particles per mu^2) on a spot and high particle surface density (greater than 0.1 particles per mu^2) on a spot are also disclosed which are viewed to be inclusive of instant claims 442-444.

Analytes include industrial and pharmaceutical compounds of all types, proteins, peptides, hormones, nucleic acids, lipids, and carbohydrates, as well as biological cells and organisms of all kinds Which are viewed to be inclusive of instant claims 12-18. One or another mode of practice of this invention can be adapted to most assay formats

which are commonly used in diagnostic assays of all kinds. For example, these include heterogeneous and homogeneous assay formats which are of the sandwich type, aggregation type, indirect or direct and the like. Sample types can be liquid-phase, solid-phase, or mixed phase. In some assay applications, the particles are bound to a solid substrate such as a bead, surface such as the bottom of a well, or the like.

5. Claims 3, 9, 10, 22, 433-441 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jezia Riley whose telephone number is 703-305-6855. The examiner can normally be reached on 9:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

JEZIA RILEY
PRIMARY EXAMINER

April 5, 2003